Purcell 9/26/97
HFI-35
409

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(617)279-1675 FAX: (617)279-1742

WARNING LETTER

NWE-14-97W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 8, 1997

Christopher P. Stowell, M.D., Ph.D.
Director, Blood Transfusion Service
General Hospital Corporation
55 Fruit Street
Boston, MA 02114

Dear Dr. Stowell:

During an inspection of The General Hospital Corporation's Blood Bank, Boston, Massachusetts on August 25 through 28, 1997, our investigators documented violations of Section 501 (a) (2) (B) of the Federal Food, Drug, and Cosmetic Act and Title 21 of the Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

Failure to maintain complete and accurate records from which donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(e)]. For example:

- Your donor deferral list does not include a donor who was repeatedly reactive for HIV 1/2 Antibody. Your own procedure, "HIVAB HIV-1/HIV-2", states that this donor should be permanently deferred.

- Your donor deferral list does not include twenty six donors who were repeatedly reactive for the Hepatitis C Virus Recombinant Enzyme Immunoassay. Your own procedure, "Hepatitis C Virus (HCV) Recombinant Enzyme Immunoassay 2.0", states that these donors should be permanently deferred.

- Your donor deferral list does not include a donor who was indeterminate for the Human T-Lymphotropic Vitus Type I (HTLV-I) Enzyme Immunoassay. Your own procedure, "Human T-Lymphotropic Virus Type I (HTLV-I) Enzyme Immunoassay [redacted], states that this donor should be permanently deferred.

- Your donor deferral list does not include two donors who had confirmed positive viral test results for Syphilis. Your own procedure, " Rapid Plasma Reagin (RPR) Test for Serologic Detection of Syphilis", states that these donors should be deferred for twelve months.

- Your software system which is used to defer donors, does not flag subsequent donations of donors who previously tested positive for certain viral markers. Your procedure, "Computer Entry of Donor Deferrals", describes four donor status codes (N-Normal, D-temporarily deferred, P-permanently deferred and R-permanently deferred allogenic donor but acceptable autologous donor). However, the software system interprets R to mean Rare and does not flag the donation as "deferred".

Failure to follow adequate written standard operating procedures [21 CFR 606.100(b)]. For example:

- In the above four referenced SOP's entitled "HIVAB HIV-1/HIV-2", "Hepatitis C Virus (HCV) Recombinant Enzyme Immunoassay [redacted]", "Human T-Lymphotropic Virus Type I (HTLV-I) Enzyme Immunoassay [redacted]"and" Rapid Plasma Reagin (RPR) Test for Serologic Detection of Syphilis", you failed to follow your own procedures to defer donors who had previously tested positive for these viral markers.

- Outdated procedures of, "Collection of a Whole Blood Unit" were observed being used in the blood collection area and the mobile unit.

- The "Donor Information Brochure" (DIB) referenced in SOP, "Interview of Volunteer, Designated, and Honorary Donors" is not the most recent brochure being provided to donors during registration.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as Medical Director to assure that your establishment is in compliance with all requirements of the Federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure, and/or injunction .

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Karen N. Archdeacon, Compliance Officer, U. S. Food and Drug Administration, New England District Office, One Montvale Avenue, Stoneham, MA 02180.

Sincerely,

John R. Marzilli
District Director
New England District